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09/647,098	05/02/2001	David Grant Richards		3884

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Sughue Mion Zinn Macpeak & Seas
2100 Pennsylvania Avenue N W
Washington, DC 20037-3202

EXAMINER	
FORD, VANESSA L	

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1645	13

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/647,098	Applicant(s)	
	Examiner Vanessa L. Ford	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's preliminary amendment filed on May 20, 2001 is acknowledged. Claim 9 has been amended.

Claim Objections

2. Claim 2 is objected to because of the following informalities: What appear to be typographical errors. For example, claim 2 recites the term "additiona" which should be changed to the term "additional". Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention

3. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 1-10 are drawn to a vaccine which includes one or more strains of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said one or more strains in association with a veterinarially acceptable carrier or excipient.

Because it is not clear that cell lines possessing the properties of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 are known and publicly available or can be reproducibly isolated from nature without undue experimentation and because the claims require the use of a suitable deposit for patent purposes a deposit in a public repository is required. Without a publicly available deposit of the above *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of the cell line is an unpredictable event.

Applicant's referral to the deposit of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 on pages 5-6 of the specification is an insufficient assurance that all required deposits have been made and all the conditions of 37 CFR 1.801-1.809 have been met.

If the deposit has been made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by the International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a

patent on this application. These requirements are necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and full street address of the depository is required. If the deposits have not been made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809, assurances regarding availability and permanency of deposits are required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

> (a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request;
>
> (b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application;
>
> (c) the deposits will be maintained in the public repository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and
>
> (d) the deposits will be replaced if they should become nonviable or non-replicable.

In addition, a deposit of biological material that is capable of self-replication either directly or indirectly must be viable at the time of deposit and

during the term of deposit. Viability may be tested by the repository. The test must conclude only that the deposited material is capable of reproduction. A viability statement for each deposit of biological material not made under the Budapest Treaty must be filed in the application and must contain:

1) The name and address of the depository;
2) The name and address of the depositor;
3) The date of deposit;
4) The identity of the deposit and the accession number given by the depository;
5) The date of the viability test;
6) The procedures used to obtain a sample if test is not done by the depository; and
7) A statement that the deposit is capable of reproduction.

As a possible means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If the deposit was made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 described in the specification as filed is the same as that deposited in the depository. Corroboration may take the form of a showing a chain of custody from applicant to the depository coupled with corroboration that the deposit is identical to the biological material described in the specification and in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundack, 773 F.2d.1216, 227 USPQ (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

4. Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Claims 1-10 are drawn to a vaccine which includes one or more strains of *Eimeria* of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said one or more strains in association with a veterinarially acceptable carrier or excipient.

Despite the knowledge in the art for attenuating strains for use in coccidiosis vaccines, the specification fails to provide guidance regarding whether the *Eimeria strains* used in the claimed invention are cross-reactive since combined vaccines are encompassed by the claimed invention. The specification discloses in Example 2 that a series of trials was carried out using the vaccines containing each of the strains

produced in Example 1, combinations of 2 to 4 of these strains as well as combinations of strains according to Example 1 combined with other vaccine strains to give a vaccine (page 8). What are the other strains used in the claimed vaccine? The specification states that in "one experiment sporocysts of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97 were combined in a vaccine with Medichick strain *E. necatrix* and the Darryl strain *E. tenella* and birds were vaccinated with a vaccine containing 250 sporulated oocysts of each strain in 1 ml of saline." What antigens were isolated and used in the claimed vaccines? The specification states "all these vaccines showed excellent protection against infection with heterologous *Eimeria* strains as well as treatment of *Eimeria* infection" (page 8). Where are the data that correspond to the specification's assertion that all of the vaccines of the claimed invention were protective?

The specification fails to provide guidance regarding how to make and use the claimed invention. Protocols and procedures such as isolation of antigen, identification of other strains used in the series of trials and data obtained when animals were vaccinated/challenged with each of the claimed vaccines are not specifically provided in the Applicant's specification. The metes and bounds of the claimed invention cannot be ascertained by the information disclosed in the specification. Therefore, one of skill in the art would require guidance, in order to make or use the claimed invention in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 2 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites "unattenuate". It is unclear as to what the Applicant is referring. Correction is required.

6. Claim 8 is indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites "factured". It is unclear as to what the Applicant is referring. Correction is required.

7. Claims 1-10 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims should spell out the genus and species at the first appearance in the claims.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-4 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by or under 103(a) as being obvious over MacDonald et al *(U.S. Patent No. 5,055,292, published October 1991).*

Claims 1-4 and 7-10 are drawn to a vaccine which includes one or more strains of *Eimeria* of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said one or more strains in association with a veterinarially acceptable carrier or excipient.

MacDonald et al teach vaccines against coccidiosis in domestic fowls that contain attenuated precocious strains of *Eimeria* species (see the Abstract). MacDonald et al teach a vaccine that contains *E. aceruvlina*, *E. maxima*, *E. tenella*, *E. necatrix*, *E. mitis*, *E. brunetti* and *E. praecox* (claim 1, column 14). MacDonald et al

teach that the vaccines of their invention include chicken feed or drinking water containing the attenuated *Eimeria* strains (column 6).

MacDonald et al do not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative the strains of MacDonald, et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacterial strains of MacDonald et al in a vaccine against coccidiosis because MacDonald teach vaccines active against coccidiosis in domestic fowls that contain attenuated precocious strains of *Eimeria* species. It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by MacDonald et al would be effective in the prevention and control of coccidiosis in poultry.

9. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by or under 103(a) as being obvious over Shirley (*U.S. Patent No. 4, 438, 097, published March 29, 1994).*

Claims 1-10 are drawn to a vaccine which includes one or more strains of *Eimeria* of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said one or more strains in association with a veterinarially acceptable carrier or excipient.

Shirley teaches a vaccine composition which comprises live attenuated strains of *Eimeria* species in particular *E. necatrix* and *E. acervulina*. Shirley teaches that the *Eimeria* species may be in the form of sporocysts and that other *Eimeria* species such as *E. maxima*, *E. brunetti, E. mivati, E. tenella* and *E. praecox* may be added to provide a fully effective coccidiosis vaccine (column 4, lines 35-41). Shirley teaches that other vaccines comprising antigenic material from other species of organisms besides *Eimeria* may be used in the invention (column 4, lines 54-56). Shirley teaches that the vaccines are formulated using a sterile aqueous medium which may contain suspension agents such as gelatin (column 4, lines 60-63).

Shirley does not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative, the strains of Shirley appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria/strains of Shirley in a vaccine against coccidiosis because Shirley teaches that live vaccines comprising attenuated strains of *Eimeria* species may be formulated in the feed or drinking water of animals and these vaccines are used to prevent and control coccidiosis in poultry. It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by Shirley would be effective in the prevention and control of coccidiosis in poultry.

10. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by or under 103(a) as being obvious over Schmatz et al *(WO 94/16725, published August 4, 1994).*

Claims 1-10 are drawn to a vaccine which includes one or more strains of *Eimeria* of *E. maxima* ARI-73/97, *E. acervulina* ARI-77/97, *E. tenella* ARI-11/98, *E. necatrix* MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said one or more strains in association with a veterinarially acceptable carrier or excipient.

Schmatz et al teach live sporulated oocysts that are administered to one day old chickens to provide immunity against coccidiosis without the need to provide supplemental anticoccidial therapy (see the Abstract). Schmatz et al teach that the vaccines of their invention include *E. necatix, E. acervulina, E, brunetti, E. mitis, E. mivati, E. praecox* and *E. tenella* (page 2). Schmatz et al teach that the dosages of attenuated precocious oocysts range from about 5 to 1000 oocysts per bird for each *Eimeria* species included in the vaccine (page 3). Schmatz et al teach that the vaccines of their invention are preferably administered along with other material when the chicks are first processed. Process which administers other material to the chick, such as other vaccines. Schmatz et al teach that the aqueous oral suspensions of their invention include one or more suspending agents, thickeners or preservatives (claim 7, page 10).

Schmatz et al do not specifically teach one or more strains of *E. maxima* ARI-73/97, *E. acerculina* ARI-77/97, *E. tenella* ARI-11/98, E. necatrix MCK01 and/or *E. necatrix* ARI-MEDNEC$_3$+8 or antigens of said strains. However, in the alternative, the

strains of Schmatz, et al appear to be obvious or analogous variants of the claimed vaccine strains. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the bacteria strains of Schmatz et al in a vaccine against coccidiosis because Schmatz et al teach vaccines that comprise live, attenuated, precocious strains of coccidial species, in particular *Eimeria.* It would have been expected, barring evidence to the contrary, that vaccines comprising multiple *Eimeria* species as taught by Schmatz et al would be effective in the prevention and control of coccidiosis in poultry.

Pertinent Prior Art

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure *(Shirley et al, The Veterinary Record, October 28, 1995, Jorgensen et al (Aust. Vet. Journal, Vol. 75, No. 8, August 1997 and Shirley, Br. Vet. Journal, 1992, 148, 479).*

Status of Claims

12. No claims are allowed.

Conclusion

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
June 7, 2002

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600